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| 09/974,781 | 10/10/2001 | Michael G. Kahn | FSTK 1004-1 | 8124 |

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|---|
| COBANOGLU, DILEK B |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3626 | |

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) |
|---|---|---|
| **Office Action Summary** | 09/974,781 | KAHN ET AL. |
| | Examiner | Art Unit | |
| | Dilek B. Cobanoglu | 3626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on <u>10 October 2001</u>.

2a)☐ This action is **FINAL**.       2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) <u>1-51</u> is/are pending in the application.

     4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-51</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>10 October 2001</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

     a)☐ All   b)☐ Some *  c)☐ None of:

       1.☐ Certified copies of the priority documents have been received.

       2.☐ Certified copies of the priority documents have been received in Application No. _____.

       3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

     * See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/11/2002</u>.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____ .

## DETAILED ACTION

1.      Claims 1-51 have been examined.

### *Claim Rejections - 35 USC § 112*

2.      Claims 39 to 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

> The dependent claims 39 to 41 disclose a medium according to the
>
> independent claim 34; but claim 34 discloses a method. Examiner
>
> requests a correction.

### *Claim Rejections - 35 USC § 102*

3.  The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4.      The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior

to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5.      Claims 34, 36 to 46, and 48 to 51 are rejected under 35 U.S.C. 102(e) as being

unpatentable by Brown (U.S. Patent No. 6,196,970).

A. As per clai m 34, Brown discloses a method for evaluating a clinical trial

protocol (Brown; abstract), comprising the steps of:

i.      Encoding workflow tasks of a clinical trial protocol into a database

structured according to a predetermined model (Brown; col.3, line 66 to

col. 4, line 6, col. 6,lines 43-45 and col.6, lines 1-4), said model including

slots predefined for describing respective aspects of protocol events and

slots predefined for describing temporal relationships among protocol

events, including amounts of time allowed between two or more protocol

events (Brown; col.3, lines 49-60); and

ii.     During the step encoding, identifying an operational uncertainty in

said protocol regarding a particular one of said amounts of time (Brown;

col.3, lines 49-60).

B. As per clai m 36, Brown discloses a method according to claim 34, wherein

said predetermined model comprises a predetermined object class structure and

said slots are organized into data objects defined by said object class structure

(Brown; col.4, lines 44-46).

C. As per claim 37, Brown discloses a method according to claim 36, wherein

said data objects include protocol event objects describing protocol events, and

temporal constraint objects describing temporal constraints among said protocol

event objects, each of said temporal constraint objects including at least one slot

for identifying an amount of time allowed between two or more protocol events

(Brown; col.3, lines 49-60).

D. As per claim 38, Brown discloses a method according to claim 37, further

comprising the steps of:

      i.      Instantiating a disambiguation data object defined according to said

object class structure describing said operational uncertainty (Brown;

col.4, lines 15-19),

      ii.      Associating said disambiguation data object with a temporal

constraint object which includes a slot for identifying said particular

amount of time (Brown; col.4, lines 15-19 and col. 3, lines 49-60).

E. As per claim 39, Brown discloses a method according to claim 34, wherein

said uncertainty comprises an inconsistency in said particular amount of time a

specified in said protocol (Brown; col.4, lines 15-17 and col.3, lines 49-60).

F. As per claim 40, Brown discloses a method according to claim 34, wherein

said operational uncertainty comprises vagueness in said particular amount of

time specified in said protocol (Brown; col.4, lines 15-17 and col.3, lines 49-60).

G. As per claim 41, Brown discloses a method according to claim 34, wherein

said operational uncertainty comprises omission of said particular amount of time

from protocol (Brown; col.7, lines 1-5 and col.3, lines 15-17).

H.  As per claim 42, Brown discloses a method for evaluating a clinical trial protocol, comprising the steps of:

    i.      Encoding workflow tasks of a clinical trail protocol into a database (Brown; col.3, line 66 to col. 4, line3) that includes data objects describing protocol events and relationships among protocol events (Brown; col.6, lines 43-45).

    ii.     Identifying an operational uncertainty in said protocol during said step of encoding (Brown; col.4, lines 15-17);

    iii.     Encoding said uncertainty into said database (Brown; col.6, lines 43-45); and

    iv.     In dependence upon said database, outputting a report setting forth the operational uncertainties identified in said protocol and encoded into said database (Brown; col. 5, lines 15-17 and col.6, lines 19-23).

I.  As per claim 43, Brown discloses a method according to claim 42, further comprising the step of associating said particular data object with at least one of said data objects in said database  (Brown; col.6, lines 1-4).

J.  As per claim 44, Brown discloses a method according to claim 43, wherein

    i.      said data objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among said protocol event objects (Brown; col.6, lines 58-60 and col. 7, lines 1-5),

ii.     and wherein said step of associating comprises the step of

associating said particular data object with one of said protocol event

objects or one of said temporal constraint objects in said database

(Brown; col.6, lines 1-4).

K. As per clai m 45, Brown discloses a method according to claim 42, wherein

said database is an object-oriented database (Brown; col.6, lines 39-45).

L.  As per claim 46, Brown discloses a method according to claim 42, further

comprising the step, prior to said step of outputting (Brown; col.6, lines 19-23), of

sorting a list of said operational uncertainties identified in said protocol (Brown;

col.4, lines 15-17) and encoded into said database (Brown; col.6, lines 39-44).

M. As per claim 47, Brown discloses a method according to claim 42, wherein

said step of outputting comprises the step of outputting in a tabular form the

operational uncertainties identified in said protocol and encoded into said

database (Brown; col.6, lines 19-23).

N.  As per claim 48, Brown discloses a method according to claim 42, wherein

said operational uncertainty comprises an inconsistency in said protocol (Brown;

col.4, lines 15-19).

O. As per claim 49, Brown discloses a method according to claim 42, wherein

said operational uncertainty comprises an insufficiently specified parameter in

said protocol (Brown; col.4, lines 15-19).

P. As per clai m 50, Brown discloses a method according to claim 42, wherein

said operational uncertainty comprises an omitted parameter in said protocol

(Brown; col.4, lines 15-19).

Q. As per claim 51, Brown discloses a method according to claim 42, wherein

said operational uncertainty concerns a temporal constraints among at least two

of said protocol events (Brown; col.4, lines 15-19).

## Claim Rejections - 35 USC § 103

6.      The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

7.      Claims 1 to 9, 35 and 47 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Brown (U.S. Patent No.6,196,970) in view of Friedman (U.S. Patent

No.6,055,494).

A. As per clai m 1, Brown discloses a method for evaluating a clinical trial

protocol, comprising the steps of:

　　　　　i.      Encoding workflow tasks of a clinical trial protocol into a database

(Brown; col.6, lines 43-45) that includes data objects describing protocol

events and relationships among protocol events (Brown; col.3, line 66 to

col. 4, line 3);

ii.     Identifying an operational uncertainty in said protocol during said

step of encoding (Brown; col.4, lines 15-17);

iii.    Associating said uncertainty with at least a particular one of said

objects in said database (Brown; col.4, lines 15-17); and

iv.     In dependence upon said objects in said database, displaying a

graphical-visual representation of said protocol (Brown; col.6, lines 19-23),

said graphical-visual representation including a human-perceptible

indication that said particular object has an operational uncertainty

associated therewith.

Brown fails to expressly teach the human-perceptible indication,

per se, since it appears that Brown is more directed to viewing

some portion of the protocol at a presentation screen (Brown; col.6,

lines 19-23). However, this feature is well known in the art, as

evidenced by Freidman.

In particular, Freidman discloses a system and method for medical

language extraction and encoding which the output can be

generated in the form of a printout, or as a monitor display

(Freidman; col. 1, lines 56-58) wherein different type of information

can be highlighted (Freidman; col. 4 lines 9-13).

It would have been obvious to one having ordinary skill in the art at

the time of the invention to have combined the viewing some

portion of the protocol at a presentation screen (Brown; col.6, lines

19-23) with the highlighting the different type of information with the

motivation of produce error messages (Freidman; col. 3, lines 58-

63).

B. As per clai m 2, Brown discloses a method according to claim 1, wherein said

database is an object-oriented database (Brown; col.6, lines 39-45).

C. As per claim 3, Brown discloses a method according to claim 1, wherein said

data objects include protocol event objects describing protocol events, and

temporal constraint objects describing temporal constraints among said protocol

event objects (Brown; col.6, lines 58-60 and col.7, lines 1-5).

D. As per claim 4, Brown discloses a method according to claim 3, wherein said

step of displaying comprises the step of displaying each of said data objects in a

color which differs depending on whether an operational uncertainty is

associated therewith.

> The obviousness of modifying the teaching of Brown to include the
>
> different information highlighted in color (as taught by Freidman) is as
>
> addressed above in the rejection of claim 1 and incorporated herein.

E. As per clai m 5, Brown discloses a method according to claim 1, wherein said

step of displaying comprises the step of displaying each of said data objects in a

color which differs depending on whether an operational uncertainty is

associated therewith.

The obviousness of modifying the teaching of Brown to include the

different information highlighted in color (as taught by Freidman) is as

addressed above in the rejection of claim 1 and incorporated herein.

F.  As per claim 6, Brown discloses a method according to claim 1, wherein said

operational uncertainty comprises an inconsistency in said protocol (Brown;

col.4, lines 15-17).

G.  As per claim 7, Brown discloses a method according to claim 1, wherein said

operational uncertainty comprises an insufficiently specified parameter in said

protocol (Brown; col.4, lines 15-19).

H.  As per claim 8, Brown discloses a method according to claim 1, wherein said

operational uncertainty comprises an omitted parameter in said protocol (Brown;

col.4, lines 15-19).

I.  As per claim 9, Brown discloses a method according to claim 42, wherein said

operational uncertainty concerns a temporal constraints among at least two of

said protocol events (Brown; col.4, lines 15-19).

J.  As per claim 35, Brown discloses a method according to claim 34, further

comprising the step of displaying a graphical-visual representation of said

protocol, said graphical-visual representation including a human-perceptible

indication that said particular amount of time has an operational uncertainty

associated therewith.

The obviousness of modifying the teaching of Brown to include the

different information highlighted in color (as taught by Freidman) is as

addressed above in the rejection of claim 1 and incorporated herein.

8.      Claims 10 to 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Brown (U.S. Patent No.6,196,970) in view of Cunningham (U.S Patent No. 5,832,449).

A. As per clai m 10, Brown discloses at least one computer readable medium

collectively carrying a machine readable database which includes protocol data

objects describing events of a clinical trial protocol and relationships among

protocol events of the clinical trial protocol (Brown; col.3, line 66 to col. 4, line 3),

said database further including a disambiguation comment object which identifies

an operational uncertainty in said protocol(Brown; col.4, lines 15-19), said

disambiguation comment object being associates with at least a particular one of

said objects in said database (Brown; col.4, lines 15-17).

Brown  fails to expressly teach a computer readable medium, per

se, since it appears that Brown is more directed to sending the

information to the server, which records in the database (Brown;

col.6, lines 39-44). However, this feature is well known in the art, as

evidenced by Cunningham.

In particular, Cunningham discloses a system and method for

dispensing, tracking and managing pharmaceutical trial products

wherein the system utilizes a medium, which is encoded with

specific information (Cunningham; col. 2 lines 60-63).

It would have been obvious to one having ordinary skill in the art at
the time of the invention to have combined sending the information
to the server, which records in the database (Brown; col.6, lines 39-
44) with the medium, which is encoded with specific information
(Cunningham; col. 2 lines 60-63).

B. As per clai m 11, Brown discloses a method according to claim 10, wherein
said database is an object-oriented database (Brown; col.6, lines 39-45).

C. As per claim 12, Brown discloses a medium according to claim 10, wherein
said data objects include protocol event objects describing protocol events, and
temporal constraint objects describing temporal constraint among said protocol
event objects (Brown; col.6, lines 58-60 and col.7, lines 1-5).

D. As per claim 13, Brown discloses a medium according to claim 12, wherein
said disambiguation comment object is associated with one of said protocol
event objects (Brown; col.4, lines 15-17).

E. As per clai m 14, Brown discloses a medium according to claim 12, wherein
said disambiguation comment object is associated with a particular one of said
temporal constraint objects (Brown; col.6, lines 58-60).

F. As per claim 15, Brown discloses a medium according to claim 14, wherein
said operational uncertainty concerns the amount of time allowed to elapse
between two protocol events identified by said particular temporal constraint
object (Brown; col.3, lines 49-60).

G. As per claim 16, Brown discloses a medium according to claim 12, wherein said data objects further include workflow task objects (Brown; col.5, lines 62-65).

H. As per claim 17, Brown discloses a medium according to claim 16, wherein each of said workflow task objects is associated with at least one of said protocol objects (Brown; col.6, lines 1-4).

I. As per claim 18, Brown discloses a medium according to claim 16, wherein said disambiguation comment object is associated with one of said workflow task objects (Brown; col.4, lines 15-19).

J. As per claim 19, Brown discloses a medium according to claim 10, wherein said operational uncertainty comprises an inconsistency in said protocol (Brown; col.4, lines 15-19).

K. As per clai m 20, Brown discloses a medium according to claim 10, wherein said operational uncertainty comprises an insufficiently specified parameter in said protocol (Brown; col.4, lines 15-19).

L. As per claim 21, Brown discloses a medium according to claim 10, wherein said operational uncertainty comprises an omitted parameter in said protocol (Brown; col.4, lines 15-19).

M. As per claim 22, Brown discloses a medium according to claim 10, wherein said operational uncertainty concerns the amount of time allowed to elapse between two of said protocol events (Brown; col.3, lines 49-60).

N. As per claim 23, Brown discloses at least one computer readable medium collectively carrying a machine readable database which includes protocol event objects describing events of a clinical trial protocol and temporal constraint objects describing temporal relationships among said protocol event objects, (Brown; col.3, line 66 to col. 4, line 3), at least a particular one of said temporal constraint objects identifying an amount of time between at least two of said protocol events (Brown; col.3, lines 49-60).

> The obviousness of modifying the teaching of Brown to include the computer readable medium (as taught by Cunningham) is as addressed above in the rejection of claim 10 and incorporated herein.

O. As per claim 24, Brown discloses a medium according to claim 23, wherein said database is an object-oriented database (Brown; col.6, lines 39-45).

P. As per clai m 25, Brown discloses a medium according to claim 23, wherein said database further includes workflow task objects (Brown; col.5, lines 62-65).

Q. As per claim 26, Brown discloses a medium according to claim 23, wherein said amount of time describes the time that a hypothetical patient is expected to take between first and second identified ones of said protocol event objects (Brown; col.3, lines 49-60).

R. As per claim 27, Brown discloses a medium according to claim 23, wherein said particular temporal constraint object identifies said amount of time by identifying at least one member of the group consisting of minimum and maximum times (Brown; col.3, lines 49-60).

S. As per clai m 28, Brown discloses a medium according to claim 27, wherein said particular temporal constraint object identifies said amount of time by identifying both members of the group consisting of minimum and maximum times (Brown; col.3, lines 49-60).

T. As per claim 29, Brown discloses a medium according to claim 28, wherein said particular temporal constraint object identifies said amount of time further by identifying a base time between said minimum and maximum times (Brown; col.3, lines 49-60).

U. As per claim 30, Brown discloses a medium according to claim 23, wherein said database further includes a disambiguation comment object associated with said particular temporal constraint object, said disambiguation comment object identifying an operational uncertainty in a particular temporal relationship identified in said temporal constraint object (Brown; col.4, lines 15-17).

V. As per clai m 31, Brown discloses a medium according to claim 23, wherein said operational uncertainty comprises an inconsistency in one of said temporal relationships as specified in said protocol (Brown; col.4, lines 15-17).

W. As per claim 32, Brown discloses a medium according to claim 23, wherein said operational uncertainty comprises vagueness in one of said temporal relationships as specified in said protocol (Brown; col.4, lines 15-17).

X. As per clai m 33, Brown discloses a medium according to claim 23, wherein said operational uncertainty comprises omission of one of said temporal relationships as specified in said protocol (Brown; col.7, lines 1-5).

## *Conclusion*

9.      The prior art made of record and not relied upon is considered pertinent to

applicant's disclosure. The cited but not used prior art teach "Computed medical file and

chart system" 5,812,983, "Method for entering information into an electronic patient

chart, and protocol auto-negative capabilities" 5,812,984," Method and apparatus for

electronically accessing and distributing personal health care information and services

in hospitals and homes" 5,867,821, "Method and system for interactive prescription and

distribution of prescriptions in conducting clinical studies" 5,991,731, "Systems, methods

and computer program products for guiding the selection of therapeutic treatment

regimens" 6,081,786," Interpolative method and system for producing medical charts

and monitoring and recording patient conditions" 6,081,809, "Research data collection

and analysis" 2002/0016530. Also, cited but not used non-patent literature include

"Decision support for clinical trial eligibility determination in breast cancer"; L Ohno-

Machado, SJ Wang, P Mar, AA Boxwala-Proc AMIA Symp, 1999, "EON: A component-

based approach to automation of protocol-directed therapy"; MA Musen, SW Tu, AK

Das, Y Shahar-J Am Med Inform Assoc., 1996, "Unitized data system: Anew formalism

for encoding and presenting data from the scientific research literature"; DP Fan, JM

Curtsinger, L Johnson, S Kalkhar- Journal of the American Society for Information

Science, 1992. Any inquiry concerning this communication or earlier communications

from the examiner should be directed to Dilek B. Cobanoglu whose telephone number is

571-272-8295. The examiner can normally be reached on 8-4:30.

10.     If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph Thomas can be reached on 571-272-6776.  The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

11.     Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system.  Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).


Dilek B. Cobanoglu
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